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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,597	05/15/2001	Wai C. Wong	45704-GA/JPW/BJA	9652

7590

05/05/2003

John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

11

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/855,597

Applicant(s)
WONG et al.

Examiner
Brenda Coleman

Art Unit
1624



– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 19, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-23, 25, 27-31, 41, 42, 45, and 53-58 is/are pending in the application.
- 4a) Of the above, claim(s) 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-18, 20-23, 25, 27-31, 41, 42, 45, and 53-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10 6) ☐ Other:

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DETAILED ACTION

Claims 13-23, 25, 27-31, 41, 42, 45 and 53-58 are pending in the application.

This action is in response to applicant's amendment filed February 19, 2003. Claim 13, 17 and 58 were amended.

Response to Amendment

Applicant's arguments filed February 19, 2003 have been fully considered with the following effect:

1. The applicants are reminded that claim 19 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.
2. The applicants amendments are sufficient to overcome the improper Markush rejection of the last office action, which is hereby **withdrawn**.
3. The applicants are reminded that the information disclosure statement filed May 15, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Several of the journal articles were

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missing from the parent application. The applicants' are requested to provide a copy of those references not initialed so that the record may be completed.

4. The applicants amendments are sufficient to overcome the 35 USC § 112, first paragraph rejections labeled paragraphs 5-8 in the last office action, which are hereby **withdrawn**.

5. The applicants amendments are sufficient to overcome the 35 USC § 112, second paragraph rejections of the last office action, which are hereby **withdrawn**.

6. The applicants amendments are sufficient to overcome the 35 USC § 102, anticipation rejections labeled paragraphs 10-11 in the last office action, which are hereby **withdrawn**.

7. The applicants amendments are sufficient to overcome the 35 USC § 103, obviousness rejection of the last office action, which are hereby **withdrawn**.

8. The applicants amendments are sufficient to overcome the obviousness-type double patenting rejections labeled paragraphs 14-17 in the last office action, which are hereby **withdrawn**.

In view of the amendment dated February 19, 2003, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 13-16, 20-23, 25, 27-31, 41, 42 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the definition of X where X is NR_3 is not described in the specification for the genus.

Applicant is required to cancel the new matter in the reply to this Office action.

10. Claims 13-17, 20-23, 25, 27-31, 41, 42 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the definition of R_5 where the aryl and heteroaryl of R_5 can be substituted with the following moieties COR_4 , CO_2R_4 , $-\text{CON}(\text{R}_4)_2$, $-\text{N}(\text{R}_4)_2$, $-\text{OR}_4$, SR_4 , $(\text{CH}_2)_6\text{OR}_4$, $(\text{CH}_2)_6\text{SR}_4$, which are not described in the specification for the genus.

Applicant is required to cancel the new matter in the reply to this Office action.

11. Claims 13-16, 20-23, 25, 27-31, 41, 42 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way

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as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the definition of R_5 where the aryl and heteroaryl of R_5 can be substituted with the following moieties COR_4 , CO_2R_4 , $-CON(R_4)_2$, $-N(R_4)_2$, $-OR_4$, SR_4 , $(CH_2)_oOR_4$, $(CH_2)_oSR_4$, which are not described in the specification for the genus.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 13-15, 17, 18, 20-23, 25, 27-31, 41, 42, 45 and 53-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 13-15, 20-23, 25, 27-31, 41, 42 and 45 are vague and indefinite in that it is not known what is meant by the definition of Z' , since there is no variable Z' in the formulae as claimed herein.
- b) Claims 13-15, 20-23, 25, 27-31, 41, 42 and 45 are vague and indefinite in that it is not known what is meant by the definition of D , since there is no variable D in the formulae as claimed herein.

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- c) Claims 13-15, 20-23, 25, 27-31, 41, 42 and 45 are vague and indefinite in that it is not known what is meant by the definition of W, since there is no variable W in the formulae as claimed herein.
- d) Claims 13-15, 20-23, 25, 27-31, 41, 42 and 45 are vague and indefinite in that it is not known what is meant by the definition of R₈, since there is no variable R₈ in the formulae as claimed herein.
- e) Claim 17 recites the limitation "R₄" on the nitrogen containing hetero ring. There is insufficient antecedent basis for this limitation in the claim. Claim 16 from which claim 17 depends is substituted on the nitrogen containing hetero ring by R₅, R₆ and R₇ not R₅, R₆ and R₄.
- f) Claim 18 recites the limitation "H₃C-O-" attached to the carbonyl at the 5-position of the pyrimidine ring in both of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which claim 18 depends is substituted on the carbonyl by R₄ which is not defined in claim 13 as H₃C-O-.
- g) Claim 18 recites the limitation "4-fluorophenyl" in the first species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which claim 18 depends is substituted on the piperidine ring by R₅, R₆ and R₄ of which only R₅ can be an phenyl ring substituted with a fluoro group.
- h) Claim 18 recites the limitation "4-methylphenyl" in the second species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which

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claim 18 depends is substituted on the piperidine ring by R_5 , R_6 and R_4 of which only R_5 can be an phenyl ring substituted with a methyl group.

- i) Claim 53 recites the limitation "phenyl" in the structure of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which claim 53 depends is substituted on the piperidine ring by R_5 , R_6 and R_4 of which none of the substituents can be an unsubstituted phenyl.
- j) Claim 53 recites the limitation " H_3C-O- " attached to the carbonyl at the 5-position of the pyrimidine ring in the structure of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which claim 53 depends is substituted on the carbonyl by R_4 which is not defined in claim 13 as H_3C-O- .
- k) Claim 54 recites the limitation "phenyl" in the structure of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which claim 54 depends is substituted on the piperidine ring by R_5 , R_6 and R_4 of which none of the substituents can be an unsubstituted phenyl.
- l) Claim 54 recites the limitation " H_3C-O- " attached to the carbonyl at the 5-position of the pyrimidine ring in the structure of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which claim 54 depends is substituted on the carbonyl by R_4 which is not defined in claim 13 as H_3C-O- .

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- m) Claim 55 recites the limitation "phenyl" in the structure of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which claim 55 depends is substituted on the piperidine ring by R_5 , R_6 and R_4 of which none of the substituents can be an unsubstituted phenyl.
- n) Claim 55 recites the limitation "cyano" in the structure of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which claim 55 depends is substituted on the piperidine ring by R_5 , R_6 and R_4 of which none of the substituents can be a cyano group.
- o) Claim 55 recites the limitation "H₃C-O-" attached to the carbonyl at the 5-position of the pyrimidine ring in the structure of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which claim 55 depends is substituted on the carbonyl by R_4 which is not defined in claim 13 as H₃C-O-.
- p) Claim 56 recites the limitation "phenyl" in the structure of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which claim 56 depends is substituted on the piperidine ring by R_5 , R_6 and R_4 of which none of the substituents can be an unsubstituted phenyl.
- q) Claim 56 recites the limitation "CH₃-O-C(=O)-" in the structure of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from

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which claim 56 depends is substituted on the piperidine ring by R_5 , R_6 and R_4 of which none of the substituents can be the moiety $\text{CH}_3\text{-O-C(=O)-}$.

- r) Claim 56 recites the limitation " $\text{H}_3\text{C-O-}$ " attached to the carbonyl at the 5-position of the pyrimidine ring in the structure of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which claim 56 depends is substituted on the carbonyl by R_4 which is not defined in claim 13 as $\text{H}_3\text{C-O-}$.
- s) Claim 57 recites the limitation "phenyl" in the structure of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which claim 57 depends is substituted on the piperidine ring by R_5 , R_6 and R_4 of which none of the substituents can be an unsubstituted phenyl.
- t) Claim 57 recites the limitation " $\text{CH}_3\text{-O-}$ " in the structure of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 13 from which claim 57 indirectly depends excludes this moiety by proviso.
- u) Claim 57 recites the limitation " $\text{H}_3\text{C-O-}$ " attached to the carbonyl at the 5-position of the pyrimidine ring in the structure of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which claim 57 depends is substituted on the carbonyl by R_4 which is not defined in claim 13 as $\text{H}_3\text{C-O-}$.

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- v) Claim 58 recites the limitation "phenyl" in the structure of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which claim 58 depends is substituted on the piperidine ring by R₅, R₆ and R₄ of which none of the substituents can be an unsubstituted phenyl.
- w) Claim 58 recites the limitation "CH₃-O-C(=O)-" in the structure of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which claim 58 depends is substituted on the piperidine ring by R₅, R₆ and R₄ of which none of the substituents can be the moiety CH₃-O-C(=O)-.
- x) Claim 58 recites the limitation "H₃C-O-" attached to the carbonyl at the 5-position of the pyrimidine ring in the structure of the species. There is insufficient antecedent basis for this limitation in the claim. Claim 17 from which claim 58 depends is substituted on the carbonyl by R₄ which is not defined in claim 13 as H₃C-O-.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 13-18, 20-23, 25, 27-31, 41, 42, 45, 53-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/730,458. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the instant invention are embraced by the compounds, compositions and method of use of copending Application No. 09/730,458.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Finality is deemed proper notwithstanding new obviousness double patenting rejection since applicants were privy to the disclosure of the copending Application No. 09/730,458 having inventors in common and thus identification of such could have been readily made at a much earlier time in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner

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can normally be reached on Mondays from 8:30 AM to 5:00 PM, on Tuesdays from 8:00 AM to 4:30 PM, on Wednesday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for “unofficial” purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink that reads "Brenda Coleman". The signature is written in a cursive, flowing style.

Brenda Coleman
Primary Examiner AU 1624
May 2, 2003